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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,977	09/27/2001	Francis Beaulieu	QA0233 NP	5178

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EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,977	BEAULIEU ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) ✓ ✓
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's claim of priority to a provisional application under 35 U.S.C 119(e) is acknowledged. Claims 1-19 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claims 1 and 10 recite limitations of $(R_4)_n$ and $(R_3)_m$. With "*m*", and "*n*" can be 0, R_4 and R_3 do not exist. Therefore, when "*m*", or "*n*" is 0, one of the benzo ring has incomplete valence.

b. Claim 19 lacks antecedent basis because it recites "breast cancer, prostate cancer, or Hodgkin's lymphoma", which is not recited in claim 16.

c. Claims 2-9, and 11-18 are rejected as being dependent on either claim 1 or 10, and carrying over limitations of claim 1 or 10.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of Enablement:** Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inhibition of TNFα, does not reasonably provide enablement for the treatment of cancers, inflammatory and/or immune disease or disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

(1) The quantity of experimentation necessary;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The breadth of the claims;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The specification provides bioassays for the inhibition of TNFα's production, or TNFα's stimulation. The results of said assays do not suggest the efficacy of the claimed compounds in the treatment of cancers, inflammatory, and/or immune disease. The specification does not provide data for the reduction of tumor size, or inflammation (in terms reduction of pain, and/or swelling of joints, or muscles), nor does it describe a procedure for the bioassay of antiviral activity (i.e., anti HIV, or HSV-1). Furthermore, there is no guidance as to which of these compounds can treat inflammation, or tumors, and which can treat immune diseases. Currently, inflammation is known to be related to prostaglandin E, or leukotrienes, and treated with steroids, NSAID's, or leukotriene inhibitors. Regarding the treatment of prostate and breast cancers, drugs such as: finasteride and tamoxifen are used. As for HIV, and HSV-1 infections, reverse transcriptase inhibitors are known therapeutic agents. At the present, there is no "one agent" that can treat inflammation, viral infections, and cancers. Moreover, the treatment of cancers usually weakens one's immunity system. Therefore, it is contradicting for an agent to treat cancers and viral infections at the same time.

The state of the art, **Barrish et. al.** (WO 99/09845), relates mainly tricyclic compounds to immunologic disorders only. Although said teaching touches on tetracylic compounds, it is rather diffusive because there is no preferred embodiment for a benzo fused imidazo[1,5-a]quinoxaline compound as claimed herein. Hence, said teaching does not allow one skilled in the art to make an inference that a benzo-fused imidazo[1,5-a]quinoxline could exert an effect on inflammation, cancers, or immune diseases. Thus given an unpredictable nature of the

pharmaceutical art, and the limited guidance provided, undue experimentation is inevitable. See *In re Ferens*, 163 USPQ 609, and *Genetech vs. Novo Nordisk*, 42 USPQ 2nd 1001, 1006 regarding evidence required for a skilled scientist to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Tamthom N. Truong
Examiner
Art Unit 1624

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April 17, 2003